

Dietary Supplement Stakeholder Meeting
July 20, 1999, Roybal Auditorium
PANEL V (Consumers/Patient Advocates)
HEALTH PRODUCTS CLAIMS ALERT
John Earl Buttolph, Exec. Director

Good afternoon ladies and gentlemen. I'm John Buttolph and I am the founder of Health Product Claims Alert, a consumer group whose purpose is to warn the public about companies using false, misleading or unsubstantiated claims to sell their products.

Let me begin by stating that our organization supports the consumer's informed use of dietary supplements to achieve a more balanced and nutritious diet. But the consumer is not interested merely in the claims made for these products, but expects companies marketing these products to provide truthful information in compliance with existing law, particularly DSHEA. Unfortunately in the current regulatory environment, many companies are ignoring the law with impunity, and are making unsubstantiated and dangerous claims for their products' curative powers. I'm here today to urge FDA in the strongest terms to place enforcement of DSHEA as its highest priority.

Until recent statements by the new Commissioner that FDA has all the authority it needs to regulate dietary supplements, the agency seemed to be on a mission to convince the public that its hands were tied, and that in passing DSHEA Congress took away its ability to regulate supplements. At times the agency has appeared more willing to complain about its alleged lack of authority than to use its actual authority to enforce the law.

Consequently it's no wonder that a handful of companies are taking advantage of this regulatory vacuum to the detriment of those companies working within the framework of the law. Take for example E - Excel, a multi-level operation based in Springville, Utah. This is the first company my organization has focused on - there will be others - and we recently completed an extensive review of its products, promotional materials, labels and labeling.

It's hard to imagine a company more aggressive in its violation of the law than E - Excel, which appears to operate in a regulatory framework of its own, and raises profound doubts about FDA's commitment to enforcing the law in the nutritional supplements industry.

E-Excel's founder, Jau-fei Chen professes to have discovered a new science called "nutritional immunology", in which she asserts that when the cells of the immune system are properly nourished by E- Excel's products, they can mount attacks on cancers and viruses and successfully defend the body against disease. E-Excel claims that since most foods are tainted by pesticides and preservatives, only certain pure foods can properly nourish the immune system, and these foods are marketed by E-Excel.

These products are sold through a well-developed multi-level distribution system, supported by the company's extensive promotional materials and publications. Many of these products are not correctly labeled as foods. They contain no nutrition facts panel. They are not labeled in conformity with dietary supplement laws. They do not contain required ingredient information, nutrition information, or disclaimers of the miraculous curative effects claimed in the promotional materials.

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For example, E Excel promotional materials claim that Phytocopia (a cookie), Noco (a blend of plant foods), Enjoi (a lotus based beverage), Herba (an all natural beverage) and Nutria (a soy-based beverage) can "treat", "prevent" and "fight" cancer, or contain "anti-cancer properties". Promotional materials for a cactus drink, Millenium, claim that cactus can be used as a remedy for "insulin-dependent diabetes." The claims made for these products violate existing law, apparently with impunity. How many consumers have discarded their more effective medications based upon these unsubstantiated claims?

This company and its founder Jau-fei Chen were warned by FDA in 1989 that her label claims for the product True Balance could make the product an illegal, unapproved drug. According to an FDA document, Ms. Chen promised to redesign her labels and submit draft copies to the FDA office in Denver for review. We could find no record of any follow-up on her part, or by FDA. Then in 1992, she was charged with a federal felony for mislabeling imported gloves, pled guilty and paid more than \$184,000. in fines. During a more recent FDA inspection, the company's vice-president denied having any marketing literature, brochures or product catalogs for seven of its products. However, the company's multi-level marketers quote extensively from promotional materials in selling these products.

In the case of E Excel enforcement action is long overdue. Later this week, my organization will file a Citizen Petition demanding the agency take administrative action to enjoin the company's unlawful labels and its promotion of food products as drugs. We are also asking that consumers who have purchased E Excel products be notified of the agency's findings and permitted to obtain refunds.

Health Product Claims Alert will continue to notify consumers of companies using false and misleading claims to sell their products. Thank you for your attention.